

PH

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FILED

1-9-14
JAN 9 2014

THOMAS G BRUTON
CLERK, U.S. DISTRICT COURT

UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL],)

Plaintiffs,)

v.)

[UNDER SEAL],)

Defendants.)

Case No. 09 C 6994

JURY TRIAL DEMANDED

REDACTED COMPLAINT

FILED IN CAMERA AND UNDER SEAL

Pursuant to 31 U.S.C. § 3730(b)(2)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF CALIFORNIA *ex rel.*)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF DELAWARE *ex rel.*)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE DISTRICT OF COLUMBIA *ex rel.*)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF FLORIDA *ex rel.*)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF GEORGIA *ex rel.*)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF HAWAII *ex rel.* ANITA)
HSIEH, KARA HARRIS, and IAN CLARK; THE)
STATE OF ILLINOIS *ex rel.* ANITA HSIEH,)
KARA HARRIS, and IAN CLARK; THE STATE)
OF INDIANA *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
LOUISIANA *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
MASSACHUSETTS *ex rel.* ANITA HSIEH,)
KARA HARRIS, and IAN CLARK; THE STATE)
OF MICHIGAN *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
MONTANA *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
NEVADA *ex rel.* ANITA HSIEH, KARA HARRIS,)
and IAN CLARK; THE STATE OF)
NEW HAMPSHIRE *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
NEW JERSEY *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
NEW MEXICO *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
NEW YORK *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
OKLAHOMA *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)
RHODE ISLAND *ex rel.* ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; THE STATE OF)

Chief Judge Holderman

09C 6994
Case No. _____

JURY TRIAL DEMANDED

FILED IN CAMERA AND
UNDER SEAL

JUDGE HOLDERMAN

MAGISTRATE JUDGE COX

RECEIVED

NOV 06 2009

MICHAEL W. DOBBINS
CLERK, U. S. DISTRICT COURT

TENNESSEE <i>ex rel.</i> ANITA HSIEH, KARA)
HARRIS, and IAN CLARK; and THE STATE OF)
TEXAS <i>ex rel.</i> ANITA HSIEH, KARA HARRIS,)
and IAN CLARK; THE STATE OF VIRGINIA <i>ex</i>)
<i>rel.</i> ANITA HSIEH, KARA HARRIS, and IAN)
CLARK; THE STATE OF WISCONSIN <i>ex rel.</i>)
ANITA HSIEH, KARA HARRIS, and IAN)
CLARK,)
)
Plaintiffs,)
)
v.)
)
SHIRE PLC and SHIRE US INC.,)
)
Defendants.)

COMPLAINT

Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark, by their undersigned counsel, Goldberg Kohn, Robin Potter & Associates, P.C. and Fern Wolf & Associates, for their complaint against Shire PLC and Shire US Inc. (collectively, "Shire"), state as follows:

NATURE OF THE CASE

1. This is an action brought under the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1, *et seq.*; the California False Claims Act, Cal. Gov't Code §§ 12650, *et seq.*; the Delaware False Claims and Reporting Act, 6 Del. Code §§ 1201, *et seq.*; the District of Columbia False Claims Act, D.C. Code §§ 2-308.03, *et seq.*; the Florida False Claims Act, Fla. Stat. §§ 68.081, *et seq.*, the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168, *et seq.*, the Hawaii False Claims Act, Hawaii Rev. Stat. §§ 661-21, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1, *et seq.*; the Louisiana False Claims Act, La. Rev. Stat. 46: §§ 437.1, *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5, *et seq.*, the Michigan

Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601, *et seq.*, the Montana False Claims Act, Mont. Code §§ 17-8-401, *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. §§ 357.010, *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61, *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. §§ 27-14-1, *et seq.*; the New York False Claims Act, State Fin. Law §§ 187, *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §§ 5053, *et seq.*, the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.*, the Texas Medicaid Fraud Protection Act, Tex. Hum. Res. Code Ann. §§ 36.001, *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1, *et seq.*; and the Wisconsin False Claims Act, Wis. Stat. § 20.931 (collectively, the “False Claims Acts”) to recover damages and civil penalties from Shire on behalf of the United States of America and the States of Illinois, California, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin (collectively, the “Government”).

2. This case centers on the illegal sales practices committed by Shire to protect it from the significant revenue loss it anticipated when the patent on its largest selling product expired in April, 2009. Unwilling to accept the reduction in revenues caused by generic competition, Shire engaged in illegal marketing of its new drugs so that it would continue to be able to sell a patented drug free from generic competition. This case raises important red flags about what happens when a pharmaceutical company engages in massive fraud to recoup lost profits when its leading product faces patent expiration and competition from generics.

INTRODUCTION

3. For the last eight years Shire has marketed and sold a drug called Adderall XR ("Adderall") to treat Attention Deficit Hyperactivity Disorder ("ADHD"). Since its approval by the Food and Drug Administration ("FDA") in 2001, sales of Adderall have grown exponentially and, by 2007, accounted for more than 40% of Shire's revenues. Further, through Adderall, Shire controls approximately 30% of the market for ADHD prescription medication. But Shire's Adderall lost patent protection in April 2009. In years prior to the expiration, Shire expected competition with generics to cut deeply into Adderall's market share and Shire's profits. Shire's financial success depended on its ability to replace Adderall and the nearly \$1 billion in annual sales which it generated.

4. In 2007, the FDA approved a new ADHD drug called Vyvanse. Shire believed that it could transform Vyvanse into the new market leader for ADHD. Accordingly, Shire purchased the company that created Vyvanse. But in order to protect the ability to continue to reap the profits associated with a patented drug, Shire needed doctors to switch patients from their existing regimen of Adderall, which would soon be subject to generic replacement. Shire chose to pay its vast network of doctors who see patients suffering from ADHD to switch those patients from Adderall to Vyvanse.

5. Shire accomplished its illegal doctor remuneration scheme by creating financial incentives for doctors to write Vyvanse prescriptions. These financial incentives were nothing more than cash payments to doctors who would agree to "ride along" with Shire sales representatives when they called on other doctors and help the representatives to convince the doctors to switch their patients from Adderall to Vyvanse. They also paid the doctors to speak to large groups of other doctors in order to convince them to write Vyvanse prescriptions.

6. Only doctors who wrote large numbers of Vyvanse prescriptions would qualify for those financial incentives and Shire's messaging to the doctors made clear that the financial incentives were a *quid pro quo* for writing a high volume of Vyvanse prescriptions. The total of annual payments to doctors to do "ride alongs" and speaking engagements approached the doctors' annual compensation for rendering medical services. Shire's illegal payment scheme violates the federal anti-kickback law and tainted every prescription of Vyvanse—many of which wound up being covered by Medicaid.

7. In addition to paying its doctor network to prescribe Vyvanse, Shire further attempted to increase Vyvanse's market share by instructing its sales representatives to intervene surreptitiously in the preapproval process required by certain state Medicaid agencies for reimbursement of Vyvanse prescriptions.

8. For example, in Illinois, an individual patients' prescription for Vyvanse could be approved for payment by Medicaid only after a doctor attested that Vyvanse, as opposed to other drugs, was "medically necessary." In Illinois, and other states, Shire directed its sales representatives to contact Medicaid on behalf of doctors, without disclosing that the call was being placed by a Shire sales representative, and represent to the State Medicaid Agency that the Vyvanse prescription was "medically necessary," all without ever involving the doctor.

9. The False Claims Acts prohibit knowingly presenting (or causing to be presented) to the Government a false or fraudulent claim for payment or approval. The False Claims Acts also prohibit knowingly making or using a false or fraudulent record or statement to get a false or fraudulent claim paid or approved by the Government. In addition, the False Claims Acts prohibit conspiring with another person to defraud the Government by getting a false or fraudulent claim allowed or paid. The False Claims Acts also prohibit knowingly making or

using a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. Any person who violates the Federal False Claims Act is liable for civil penalties of up to \$11,000 for each violation, plus three times the amount of the damages sustained by the Government.

10. The False Claims Acts allow any person having information about false or fraudulent claims to bring an action on behalf of the Government, and to share in any recovery. Relators states that all allegations in this Complaint are based on evidence obtained directly by Relators independently and through their own labor and efforts. The information and evidence that Relators have obtained or of which Relators have personal knowledge, and on which these allegations of False Claims Acts violations are based, consist of documents and conversations that Relators have had with doctors and numerous levels of supervisors at Shire. Relators are therefore an original source of the information alleged herein, and have provided that information to the Government in advance of filing this action.

11. Pursuant to 31 U.S.C. § 3730(b)(2), Relators are providing the Government and the States with a copy of the Complaint and a written disclosure of substantially all material evidence and material information in Relators' possession.

12. In accordance with 31 U.S.C. § 3730(b)(2), the Complaint has been filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on Defendants until the Court so orders.

13. Based upon these and other provisions of the False Claims Acts, the Relators seeks through this action to recover damages and civil penalties arising from Defendants' violations of the False Claims Acts.

JURISDICTION AND VENUE

14. Jurisdiction and venue are proper in this Court pursuant to 31 U.S.C. § 3732,

which states that:

(a) Actions under section 3730.--Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under state law.--The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

15. This action is not based on a public disclosure. It is based on information that is within the direct and independent knowledge of Plaintiff-Relators. Plaintiff-Relators have provided that information to the government prior to filing this action.

PARTIES

16. Anita Hsieh ("Hsieh") is a former Shire sales representative who worked for Shire from April 2007 to July 2008. Hsieh covered the territory internally denominated as the St. Louis North region, which covered much of southern Illinois. Hsieh is a citizen of the state of Missouri. Prior to her employment at Shire, Hsieh had never worked in the pharmaceutical industry.

17. Kara Harris ("Harris") is a former Shire sales representative who worked for Shire from June 2004 to July 2008. Harris' territory was also the St. Louis North region. Harris is a citizen of the state of Illinois. Prior to her employment at Shire, Harris had never worked in the pharmaceutical industry.

18. Ian Clark ("Clark") is former Shire sales representative who worked for Shire from October 2004 to July 2008. Clark's territory was also the St. Louis North region. Clark is a citizen of the state of Illinois. Prior to his employment at Shire, Clark had never worked in the pharmaceutical industry.

19. Shire is a British pharmaceutical company organized under the laws of Great Britain, with its principle place of business in Hampshire, England. Shire US Inc. is a subsidiary of Shire PLC incorporated under the laws of New Jersey, with its principal place of business in Wayne, Pennsylvania. Shire US Inc.'s function is to market and sell Shire products in the United States, including Vyvanse.

BACKGROUND

A. History of Shire's ADHD Drugs

20. Over the past 8 years, Shire's sales of Adderall have grown every year, reaching nearly one billion dollars in 2008.

21. Despite Shire's dramatic success with Adderall, Shire has faced litigation challenging Shire's patent rights. In 2006, Shire resolved its patent dispute by agreeing to permit generic marketing of Adderall in April 2009.

22. As a consequence of the impending competition, Shire looked to develop other ADHD medication to replace Adderall. Shire believed that competition with generics would ultimately drastically reduce its Adderall sales, which represented a substantial percentage of Shire's total revenues.

23. In 2006, Shire released a new ADHD medication called Daytrana. At the time of its release, Daytrana was expected to be Shire's replacement for Adderall.

24. However, multiple product recalls undermined Shire's efforts to use Daytrana to replace Adderall. Daytrana's sales have never, therefore, approached Shire's Adderall sales. Thus, Shire continued to look for other ADHD drugs to replace Adderall.

25. In February 2007, Shire acquired Vyvanse through its purchase of New River Pharmaceuticals. Shire intended to market Vyvanse instead of Adderall with the hope and expectation that Vyvanse would replace Adderall in the marketplace. Shire launched Vyvanse in June 2007.

26. The molecular structure of Vyvanse is virtually identical to Adderall. Despite the fact that Vyvanse had little, if any, therapeutic benefit over Adderall, Shire initially expected to promote in its sales efforts the fact that Vyvanse was harder to break down (*i.e.*, crush) and abuse.

27. Initially, Shire expected Vyvanse to receive a lower regulatory classification from the FDA than Adderall had received, which would make Vyvanse prescriptions much easier for patients to refill. With the lower FDA rating, patients' doctors could simply phone in a refill order, thus saving patients a trip to the physician and pharmacy to pick up and deliver their prescriptions. Indeed, the lower regulatory classification was the sole factor that Shire expected would make Vyvanse successful.

28. Chad Hellen was the Director of one of Shire's nine sales zones, the F-Zone. In about October 2006, he explained at a "Plan-of-Action" meeting ("POA meeting") in Chicago attended by all of Shire's sales representatives for that region, that if Vyvanse got a lower regulatory classification allowing for call-in prescription refills, it would be "lights out." Mr. Hellen further told his sales representatives that without the lower classification, Vyvanse would be "just another" ADHD drug.

29. Vyvanse ultimately received the same regulatory classification as Adderall, however, thereby eliminating the main distinction between the two drugs that Shire had originally planned to promote.

B. The Vyvanse Launch

30. Following approval of Vyvanse by the FDA and Shire's purchase of Vyvanse in February 2007, Shire began preparations to market Vyvanse as the replacement for Adderall. In June of 2007, Shire held a "launch meeting" for Vyvanse in Hollywood, Florida at a Westin resort hotel (the "Vyvanse Launch Meeting").

31. The Vyvanse Launch Meeting was attended by Shire's sales force nationwide, with the purpose of motivating the sales force to market Vyvanse. Among the speakers were senior executives from Shire, including Harry Painter, National Sales Director of ADHD, and Gary Casto, Vice President of ADHD Sales. The Shire executives who spoke presented Vyvanse as the means to "secure" the company's future and render irrelevant the impending generic competition to Adderall.

32. There were numerous slide presentations at the Vyvanse Launch Meeting espousing the benefits of Vyvanse and explaining Shire's goal that Vyvanse replace Adderall in the marketplace. One of the slides frequently presented at the Vyvanse Launch Meeting depicted a grave stone, with the words "Adderall R.I.P." Cf. ADHD Weekly Report, attached hereto as Exhibit A.

33. The primary focus of the Vyvanse Launch Meeting was the importance of replacing Adderall with Vyvanse. Gary Casto and Harry Painter emphasized to the sales force the immediacy of the situation, showing slides that spurred the sales force to "*Rapidly* replace

[Adderall] prescriptions with Vyvanse.” Vyvanse Launch Meeting Slide, attached hereto as Exhibit B.

34. Other slides depicted military scenes with the caption: “The future is in your hands! Over the next 3 months, we must establish Vyvanse as a physician's first choice when prescribing ADHD medications.” Vyvanse Launch Meeting Slide, attached hereto as Exhibit C. Sales representatives were made to feel that success by any means was required to secure the company's future.

35. At the Vyvanse Launch Meeting, Shire described that the rapid replacement of Adderall should be accomplished in two ways: (1) by stopping the flow of new patients to Adderall, including patients newly diagnosed with ADHD as well as those switching from other drugs; and (2) by switching current Adderall users to Vyvanse. See Vyvanse Launch Meeting Slide, attached hereto as Exhibit D

36. Shire instructed its sales force to encourage doctors to switch patients who were doing well on Adderall, even though there was no medical or evidence-based reason to do so. Shire directed its sales representatives to provide a non-responsive answer that explained the results of studies that did not compare Adderall and Vyvanse to convince doctors to switch their patients. See Vyvanse Launch Meeting Slide, attached hereto as Exhibit E.

C. Shire Paid Doctors to Prescribe Vyvanse Through Its “Ride Along” Program.

37. The primary strategy that Shire used to convince doctors to prescribe Vyvanse instead of Adderall was to offer doctors money for prescribing Vyvanse instead of Adderall.

38. The payments were made to doctors who were “high volume” Vyvanse prescribers in exchange for the doctors’ agreement to ride along with Shire's Vyvanse sales representatives when they made their sales calls to other doctors. The ride along doctors (also

known as "speakers") helped the sales representatives convince other doctors to prescribe Vyvanse.

39. Once a doctor was in the ride along program, he/she could earn tens of thousands of dollars annually promoting Shire's drugs. To become a "ride along" doctor for Vyvanse, it was a minimum requirement that a doctor prescribe Vyvanse in large quantities. The doctors knew this and worked hard to qualify for ride alongs, which meant prescribing large amounts of whatever drug Shire was then promoting.

40. The "company line" that was communicated to the Relators (and all Shire sales representatives) through Shire's training programs and in conversations with regional and zone directors (like Relators regional and zone directors, Mr. Jackson and Mr. O'Keefe) was that doctors were chosen to be advocates because they had "experience" with the drug and were "believers" in the benefits of the drug. "Experience" and being a "believer" were pseudonyms for high prescribers.

41. From their training and constant conversations with Mr. Jackson and Mr. O'Keefe, the Relators (as well as any Shire sales representatives) knew that the only way to become a "ride along" doctor was to write more prescriptions for Shire drugs, and Relators directly communicated this fact to their doctors.

42. Shire pays "ride along" doctors \$1,500 per day for riding along with a sales representative to promote the Shire drug to doctors visited by that sales representative, and \$2,000 for a follow-up speaking engagement promoting a Shire drug. Shire pays higher profile national speakers \$2,000 per day for ride-alongs.

43. The Relators were frequently told by Mr. Jackson and Mr. O'Keefe at POA meetings that it was important to keep speakers happy by scheduling ride-alongs and paid

speaking engagements for them; that is, creating opportunities for speakers to be paid by Shire. Indeed, throughout their employment with Shire, Relators were told by Mr. Jackson, Mr. O'Keefe and Mr. Painter that they should keep their speakers happy so that those doctors would continue to write Vyvanse prescriptions.

44. In each case, the determining factor considered by Shire in selecting which doctors to pay for ride-alongs was the quantity of prescriptions for the Shire drug being written. While Shire would also select doctors thought to have sway in the medical community, this factor was secondary to the minimum requirement that ride-along doctors be high-volume prescribers of the drug Shire was promoting.

45. When sales representatives tried to "book" a speaker for a ride-along, many speakers (and particularly the national speakers) would not agree to the trip unless the sales representative would also arrange a dinner or evening event on the same day as the ride-along for which they would be paid to attend. By this double-booking, a speaker could earn \$3,500 or \$4,000 in a single day, \$1,500 or \$2,000 for the ride-along and \$2,000 for the speaking event or promotional dinner.

46. For example, Ms. Harris retained multiple national speakers who refused to come to her territory for a ride-along unless Ms. Harris was able to book a ride-along on the day of the speaker's arrival, a speaking event that evening, and another ride-along the following day. Such speakers included Dr. Susan Antonicci (a speaker for Daytrana), Dr. Frank Lopez (a speaker for Vyvanse), and Dr. Thomas Sao (a speaker for Adderall). All three doctors demanded a two-day trip, for which they could earn \$6,000.

47. By aggressively marketing themselves and insisting on back-to-back ride-alongs and paid dinner engagements, these three speakers (and there is nothing unique about these three) are believed to have earned in excess of \$100,000 from Shire.

48. Doctors who were speakers for Adderall had become reliant on the income generated by being speakers for Adderall. Once the doctors learned that Shire was no longer promoting Adderall, the doctors were anxious to transfer their patients from Adderall to Vyvanse in order to maintain their "ride along" income.

49. The doctors were told by Shire at Shire training events that Shire would no longer be paying for Adderall speakers and were instead interested in Vyvanse speakers. Accordingly, there was a substantial overlap between the national speakers who previously spoke for Adderall and those who later spoke for Vyvanse.

50. For example, Doctors Antonicci and Lopez were both national Adderall speakers who transferred their loyalty to Daytrana and Vyvanse, respectively. Additionally, Dr. Lanny Stiles and Dr. Robert Hunt were, in succession, national speakers for Adderall, Daytrana and Vyvanse. Of course, all of these doctors were top prescribers for all three drugs—all within a three-year period, from 2005-2008.

51. Shire's payments to, and as a consequence, control of its top prescribing doctors through the speaker program was a pivotal and central part of its new product launches. Indeed, at the Vyvanse Product Launch, Shire told all of its sales representatives that a high percentage of Shire's top Adderall doctors (its Adderall speakers) would be immediately transferring all of their patients to Vyvanse. These doctors were called the "early prescribers." Vyvanse Launch Meeting Slide, attached hereto as Exhibit F.

D. Ms. Hsieh's Territory Included Doctors Who Agreed To Prescribe Vyvanse In Exchange For Payments From Shire.

52. One of the doctors that Ms. Hsieh worked with frequently, Dr. Yanamadala, was an Adderall speaker before Shire shifted its marketing efforts away from Adderall. From the time Ms. Hsieh began making sales calls to Dr. Yanamadala, he frequently asked Ms. Hsieh to make him a speaker for Vyvanse.

53. Dr. Yanamadala did not discuss the medical benefits or reasons why Vyvanse might better suit his patients. Rather, Dr. Yanamadala simply told Ms. Hsieh that he wanted to become a Vyvanse speaker. Dr. Yanamadala indicated to Ms. Hsieh that he wanted to become a speaker for Vyvanse because of the high compensation he expected to receive from the position.

54. Throughout the time that Dr. Yanamadala requested that he be paid by Shire for speaking about and promoting Vyvanse, Dr. Yanamadala was not prescribing Vyvanse to his patients. Accordingly, Ms. Hsieh explained to Dr. Yanamadala, as she was trained by Shire to do, that he could not become a Vyvanse speaker unless he wrote a high volume of Vyvanse prescriptions. Dr. Yanamadala frequently responded to Ms. Hsieh's explanation by telling her that Ms. Hsieh's predecessor had made Dr. Yanamadala an Adderall speaker.

55. The implication to Ms. Hsieh was clear: if Shire made Dr. Yanamadala a Vyvanse speaker, he would write Vyvanse prescriptions. Indeed, Ms. Hsieh's understanding was confirmed by Dr. Yanamadala's secretary, Crystal Pool.

56. Ms. Pool told Ms. Hsieh several times that if she made Dr. Yanamadala a speaker, he would be happier with her and write more Vyvanse prescriptions. Ms. Hsieh's conversations with Dr. Yanamadala continued in this manner for several months.

57. Ultimately, as will be discussed more fully below, Dr. Yanamadala began prescribing Vyvanse with Ms. Hsieh's aid in obtaining prior approval so that his prescriptions

would be paid by Medicaid. Once Dr. Yanamadala began writing Vyvanse prescriptions, his conversations with Ms. Hsieh concerning remuneration from Shire changed.

58. Dr. Yanamadala frequently mentioned to Ms. Hsieh that he felt that he had earned the benefits of being a Vyvanse speaker because of the quantity of Vyvanse he was prescribing. Based on her training from Shire, Ms. Hsieh agreed that Dr. Yanamadala was a good candidate for remuneration from Shire.

59. Ms. Hsieh asked her regional director, Jeff Jackson, to approve Dr. Yanamadala as a speaker. Mr. Jackson replied that Dr. Yanamadala had to write more Vyvanse prescriptions before he would be considered for a position as a speaker. Ms. Hsieh informed Dr. Yanamadala of Shire's response. As a result, Dr. Yanamadala, with Ms. Hsieh's assistance in getting Medicaid approval, continued to write more and more Vyvanse prescriptions. Indeed, shortly before her termination, Ms. Hsieh, Mr. Jackson and Dr. Yanamadala met over lunch to discuss Dr. Yanamadala actually becoming a Vyvanse speaker.

60. Another example of Shire's payments to doctors for Vyvanse prescription is Dr. Muddasani, another doctor in Ms. Hsieh's territory.

61. From the outset of Ms. Hsieh's relationship with Dr. Muddasani, he informed Ms. Hsieh that he had previously been an Adderall speaker and wanted to become a Vyvanse speaker. Dr. Muddasani would listen to Ms. Hsieh's sales pitch for Vyvanse, but was only interested in discussing the possibility that Shire would make him a speaker.

62. As with Dr. Yanamadala, Ms. Hsieh told Dr. Muddasani that if he wanted to become a speaker for Vyvanse, he had to write Vyvanse prescriptions. Dr. Muddasani frequently responded that if Shire wanted him to prescribe Vyvanse, then Shire should make him a speaker.

Also as part of his demands that he be made a Vyvanse speaker, Dr. Muddasani told Ms. Hsieh about all the other pharmaceutical companies that were compensating Dr. Muddasani.

63. Dr. Muddasani's secretary, Bonnie, also urged Ms. Hsieh to make him a speaker. Bonnie told Ms. Hsieh that if she made Dr. Muddasani a Vyvanse speaker, Dr. Muddasani would definitely write Vyvanse prescriptions.

E. Doctors in Ms. Harris' Territory Also Sought Payments From Shire In Exchange for Vyvanse Prescriptions.

64. One of the doctors in Ms. Harris' territory was Dr. Chauray Kavuri. Dr. Kavuri aggressively demanded that he be made a Daytrana speaker when Shire was promoting that drug. He told Ms. Harris that if she made him a Daytrana speaker, he would begin writing Daytrana prescriptions.

65. Ms. Harris told Dr. Kavuri, as she was trained by Shire to do, that he must first write the prescriptions, and only then would he be considered for a speakership. Dr. Kavuri agreed to write more Daytrana prescriptions, and in exchange, Ms. Harris spoke with her superiors about a speakership. Shire ultimately agreed to make Dr. Kavuri a Daytrana speaker.

F. The Prior Authorization Requirement in Illinois For Vyvanse.

66. Many of those who suffer from ADHD rely on a state Medicaid program for their health insurance, including coverage for their prescription drugs, like Adderall. State Medicaid programs, however, will cover only the prescription drugs that are included on the state "formulary." A state Medicaid formulary lists which prescription drugs will be covered by Medicaid for a particular diagnosis. Adderall is on the Illinois formulary list.

67. After its approval by the FDA in February 2007, Vyvanse was *not* placed on the Illinois formulary list. A Vyvanse user in Illinois seeking Medicaid reimbursement for a Vyvanse prescription was required to have the prescription pre-approved by Medicaid, subject to

specified pre-approval criteria to be verified by the prescribing doctor. To satisfy those criteria, a doctor wishing to prescribe Vyvanse (or any other drug not on a state's formulary list) had to confirm that a particular prescription for Vyvanse was "medically necessary." For example, one of the requirements in Illinois was that the patient had tried at least two other ADHD medications and that the other medications had failed.

68. The fact that Vyvanse was not on the formulary list in Illinois was a substantial obstacle to convincing Illinois doctors to prescribe it, as the administrative burden associated with obtaining prior approval for Vyvanse prescriptions was not practically or economically feasible for these doctors.

69. This issue came up at the Vyvanse Launch Meeting in July 2007, when Gary Casto (Vice President of ADHD Sales) told Shire's entire sales force that they should not allow the lack of formulary coverage stop their doctors from writing Vyvanse prescriptions.

G. Sales Representatives, Including Relators, Were Directed To Obtain Prior Authorization for Vyvanse Prescriptions for Their Doctors.

70. Routinely, the sales representatives in the St. Louis North region, including Relators, would meet with Mr. Jackson, their regional director, to discuss sales methods and strategies. Mr. Jackson first directed the sales representatives to take over the prior authorization process at one of these meetings in the fall of 2007.

71. Mr. Jackson explained that Joel Mau, a regional director for one of the Chicago regions, told him that one of Mr. Mau's sales representatives, Kim Basey, had taken it upon herself to resolve the prior authorization problem at her doctors' offices. She would arrive at her doctors' offices in the morning to complete Vyvanse prior authorizations for the patients whom her doctor had seen the previous day and prescribed Vyvanse.

72. Mr. Jackson told the Relators and other sales representatives that Ms. Basey was an example of an ideal sales representative, someone who was doing what it took to get the job done. Mr. Jackson directed the Relators and other sales representatives to do the same.

73. After this meeting, the Relators went to their doctors' offices to volunteer their services to obtain prior authorization for patients for whom the doctor would prescribe Vyvanse. As previously discussed, with the administrative burden removed, the doctors had every incentive to write Vyvanse prescriptions. Some of the doctors agreed to let the Relators do the prior authorization.

74. The general process by which sales representatives, including Relators, obtained prior authorization is as follows:

- First, the Relators would supply coupons for one free month of Vyvanse to their doctors. The Relators would do so either by directly placing a coupon in each patient file by leaving a supply of coupons at the office. Because no reimbursement was required for the free month of Vyvanse, the doctor did not need prior authorization to prescribe this first month of Vyvanse.
- Second, shortly after a patient had been given one free month of Vyvanse, the doctors or their staff would set aside that patient's file for the Relators. The Relators would then review the file and, based only on their own reading of the medical file, call the Medicaid pre-approval contact to explain that the patient satisfied the pre-approval criteria and that Vyvanse was medically necessary. At no time during Relators' telephone calls to the State did they identify themselves as sales representatives of Shire, the manufacturer of the drug for which they were seeking approval.

- Over time, the Relators learned what they needed to say to obtain prior approval in a telephone call and tailored their communications to comments that had proven successful. The Relators further learned at what times of day their requests were most likely to be approved, such as calling immediately before a shift-change, when Medicaid employees may be anxious to end calls. For example, with respect to Ms. Hsieh, her approval rate from telephone calls was approximately 75%.
- Third, in the event that the Medicaid pre-approval contact would deny the Relators' prior authorization request on the telephone, the Relators would draft a letter to Medicaid for the doctor's signature, elaborating on the basis for the claim that the pre-approval criteria had been satisfied. The Relators would draft these letters in conjunction with their regional director, Jeff Jackson.
- The calls and letters to the Medicaid agencies were based solely on Shire's instructions and the Relators' own review of the medical records, and included no input from doctors or medical staff.

75. At the direction of their Regional Director, from the end of 2007 through Spring of 2008, the Relators visited their doctors frequently to conduct prior authorizations.

H. Ms. Hsieh Did Prior Authorizations For Her Doctors.

76. For example, Ms Hsieh visited Dr. Yanamadala's offices as frequently as several times each week and followed the above-described procedure. Dr. Yanamadala's secretary, Ms. Pool, would provide Ms. Hsieh with the medical files of patients who had received

their free month of Vyvanse the previous week, and Ms Hsieh would work to obtain prior authorization for future prescriptions of Vyvanse.

77. For example, on the morning of April 15, 2008, Ms. Hsieh called the Illinois Medicaid Agency to obtain prior authorization to prescribe Vyvanse for one of Dr. Yanamadala's patients ("Patient 1" – real name concealed for confidentiality). Neither Dr. Yanamadala, nor anyone else from his office, expressed to Ms. Hsieh that it was medically necessary, or even beneficial, for Patient 1 to take Vyvanse.

78. Based only on Ms. Hsieh's review of the file, she told the Illinois Medicaid Agency that Patient 1 had tried two other ADHD drugs and failed, thus making Vyvanse medically necessary. The Illinois Medicaid Agency granted prior authorization for this patient to be prescribed a 70 mg dosage of Vyvanse.

79. Upon information and belief, Patient 1 filled that prescription, and Medicaid paid for it. Upon information and belief, Patient 1 continued to receive and fill prescriptions for Vyvanse, and Medicaid continued to cover the cost of those prescriptions based on the pre-approval that Ms. Hsieh obtained on April 15, 2008.

80. Similarly, on the morning of April 16, 2008, Ms. Hsieh called the Illinois Medicaid Agency to obtain prior authorization to prescribe Vyvanse for another of Dr. Yanamadala's patients ("Patient 2" - real name concealed for confidentiality). Just as in every other instance in which she attempted to obtain a prior authorization, neither Dr. Yanamadala, nor anyone else from his office, expressed to her that it was medically necessary, or even beneficial, for this patient to take Vyvanse.

81. Based only on her review of Patient 2's file, Ms. Hsieh told the Illinois Medicaid Agency that this patient had tried two other ADHD drugs and failed, thus making

Vyvanse medically necessary. The Illinois Medicaid Agency granted prior authorization for this patient to be prescribed Vyvanse.

82. Upon information and belief, Patient 2 filled that prescription, and Medicaid paid for it. Upon information and belief, Patient 2 continued to receive and fill prescriptions for Vyvanse, and Medicaid continued to cover the cost of those prescriptions based on the pre-approval that Ms. Hsieh obtained on April 16, 2008.

83. Ms. Hsieh herself went through this process approximately 200 times on behalf of her doctors. (A copy of her notes on these processes is attached hereto as Exhibit G.) At no time did she ever identify herself to the Illinois Medicaid Agency as an employee of Shire. Ultimately, her approval rate for prior authorizations was approximately 75%.

84. Immediately after Ms. Hsieh took over the responsibility for obtaining prior authorizations, the Vyvanse market share being prescribed by her doctors grew. Over several months, the Vyvanse market share growth that Ms. Hsieh achieved was among the highest of all Shire sales representatives in the nation. Before she started doing prior authorizations, Vyvanse' market share among her doctors was approximately 2%. Because she did the prior authorizations for her doctors, that market share ultimately grew to approximately 10%.

85. These increased sales of Vyvanse were directly reflected in Ms. Hsieh's quarterly bonuses. After she took over the responsibilities for prior authorizations, the bonuses that she received quarterly grew from approximately \$1,500 to over \$20,000.

I. Ms. Harris Did Prior Authorizations For Her Doctors.

86. After the meeting in which Mr. Jackson directed Relators and other sales representatives in his region to do prior authorizations "to get the job done" (*see supra* at ¶¶ 75-77). Ms. Harris asked her doctors if she could become involved. One of the doctors solicited by

Ms. Harris was Dr. Riseman. Dr. Riseman agreed to let Ms. Harris take over the responsibility of getting prior authorization for Vyvanse, and Ms. Harris did so from March through June 2008.

87. As described above, Ms. Harris would supply Dr. Riseman's assistant, Joellen, with coupons for one free month of Vyvanse. Then, on Tuesdays, Joellen would provide Ms. Harris with the files of all those who had been given the free month of Vyvanse from the prior week, and Ms. Harris would attempt to obtain prior authorization for the patient's Vyvanse prescription.

88. For example, on April 23, 2008, Ms. Harris called the Illinois Medicaid Agency to obtain prior authorization to prescribe Vyvanse for one of Dr. Riseman's patients ("Patient 3" - real name concealed for confidentiality). Like Ms. Hsieh, Ms. Harris would not discuss the patient files with Dr. Riseman or any other medical staff in his office. Neither Dr. Riseman, nor anyone associated with him ever expressed to Ms. Harris that it was medically necessary, or even beneficial, for Patient 3 to take Vyvanse.

89. Based on her review of this file, Ms. Harris told the Illinois Medicaid Agency that Patient 3 had tried two other ADHD drugs and failed, thus making Vyvanse medically necessary. The Illinois Medicaid Agency denied prior authorization for this patient to be prescribed Vyvanse.

90. Ms. Harris then wrote a letter to the Illinois Medicaid Agency to again request prior authorization for this patient. Based on Shire's instructions, she drafted the letter on May 1, 2008, based only on her review of the patient's medical files and without any input from Dr. Riseman or anyone associated with him. Shire's Regional Director, Mr. Jackson, reviewed the proposed letter and provided his comments and edits that same day. Ms. Harris left the letter with

Dr. Riseman's office for his signature. Ultimately, Ms. Harris telephoned the Illinois Medicaid office and confirmed that Patient 3 had been approved to receive a prescription for Vyvanse.

91. Upon information and belief, Patient 3 filled that prescription, and Medicaid paid for it. Upon information and belief, Patient 3 continued to receive and fill prescriptions for Vyvanse, and Medicaid continued to cover the cost of those prescriptions based on the pre-approval that Ms. Harris obtained.

92. On May 9, 2008, Ms. Harris called the Illinois Medicaid agency on behalf of another one of Dr. Riseman's patients ("Patient 4" - real name concealed for confidentiality) to seek prior authorization for a Vyvanse prescription. Again, Ms. Harris explained to the Illinois Medicaid agent why Vyvanse was medically necessary for Patient 4 without any consultation with Dr. Riseman or anyone else from his office informing her that Vyvanse was medically necessary, or even beneficial. The prescription was approved.

93. Upon information and belief, Patient 4 filled that prescription, and Medicaid paid for it. Upon information and belief, Patient 4 continued to receive and fill prescriptions for Vyvanse, and Medicaid continued to cover the cost of those prescriptions based on the pre-approval that Ms. Harris obtained on May 9, 2008.

94. Between March and June 2008, Ms. Harris followed the above procedures to obtain approximately 25 prior authorizations for Vyvanse prescriptions. (A copy of her notes on these processes is attached hereto as Exhibit H.)

J. Prior Authorizations Were Occurring In Many States In Addition to Illinois Where Vyvanse Was Not on the State Formulary List.

95. It was not only sales representatives from the St. Louis North region that were engaged in obtaining prior authorizations. Sales representatives in other territories where Vyvanse was not on the state formulary were also obtaining prior authorizations for their doctors.

96. In addition to the Chicago regional director and sales representative (Joel Mau and Kim Basey) who first told Mr. Jackson about the benefits that could be achieved by doing prior authorizations, in or about August 2007, Ms. Hsieh received a telephone call from Keith Stout, a regional director in Southern Illinois, and Melissa Hamm, a sales representative from the Southern Illinois region, asking her how to obtain prior authorizations.

97. In or about Spring of 2008, Dr. Robert Hunt, a Shire national speaker from Tennessee, told Ms. Harris that while Vyvanse was not on the Tennessee formulary list, Shire sales representatives in that state were uniformly involved in obtaining prior authorizations for their doctors.

98. In discussions with Katherine Vickers, a former Shire sales representative, Ms. Harris also learned that sales representatives in Minnesota, including Jon Wessinger, were doing prior authorizations.

99. Likewise, an Alabama sales representative, Wendy Phillabaum, told Mr. Clark that prior authorizations were routinely done in Alabama by Shire sales representatives before Vyvanse went on the formulary list in that state.

100. In addition, in a telephone call with Ms. Harris, Keith Stout, the regional director for the St. Louis South region, admitted that he was having his sales representatives obtain prior authorizations.

101. Mark Lawler, who worked under Mr. Stout in the St. Louis South region, confessed to Ms. Hsieh that he had done hundreds of prior authorizations in Missouri.

102. The reality is that anyplace where Vyvanse was not on the state Medicaid formulary, prior authorizations were required and Shire sales representatives were engaged in obtaining prior authorizations on behalf of their doctors' offices to obtain approval for Vyvanse

prescriptions without the doctors' review of the patients' charts and without any medical necessity for Vyvanse.

K. Shire Knew That Sales Representatives Were Doing Prior Authorizations Independent of Their Doctors.

103. At all times while they were obtaining prior authorizations from Medicaid, the Relators were in constant communication with their Regional Director, Mr. Jackson, about their activities. Mr. Jackson repeatedly told the Relators that he was in communication with Zone Director Jim O'Keefe about their activities, and that Mr. O'Keefe approved.

104. In one of Ms. Hsieh's formal reviews from Mr. Jackson, he wrote in her employment review that she had done a great job building relationships with her doctors' offices, including "assisting them with doing Pas [prior authorizations], etc." Hsieh Review, attached hereto as Exhibit I. This statement specifically refers to the extensive prior authorization work that Ms. Hsieh was doing for her doctors and became part of Ms. Hsieh's official employment file at Shire.

105. Upon information and belief, upon completion, the Relators understand that regional directors were required to forward these review to zone directors.

106. In addition to Mr. Jackson's statement that he was frequently in communication with senior sales management concerning his sales representatives' involvement in obtaining prior authorizations, the Relators had at least two conversations directly with Mr. O'Keefe, the head of Vyvanse sales for Zone F, informing him of what they were doing.

107. With respect to Ms. Hsieh, in or about the Spring of 2008, she was present during a telephone conversation between Mr. Jackson and Mr. O'Keefe in which Mr. Jackson discussed Ms. Hsieh's success rate in obtaining prior authorizations.

108. Further, Ms. Hsieh and Ms. Harris both spoke to Mr. O'Keefe in early 2008 about the process by which they were obtaining prior authorizations from the Illinois Medicaid agency.

109. Ms. Harris spoke to Mr. O'Keefe in person at a POA Meeting in early 2008 to discuss the problems that she and other sales representatives were having in getting Vyvanse prescriptions authorized in Illinois. All of the sales representatives in Zone F were present at this meeting. Mr. O'Keefe did nothing to discourage Ms. Harris and the other sales representatives from themselves conducting prior authorizations. Instead, Ms. Harris understood that Mr. O'Keefe was supportive of the sales representatives' prior authorization efforts.

110. At another POA meeting in the first quarter of 2008, which all F-Zone sales representatives attended, Lauren Goldstein, a sales representative in the St. Louis South region, asked Harry Painter, National Sales Director for ADHD, about doing prior authorizations for doctors' offices. Ms. Goldstein asked Mr. Painter for tips about what sales representatives should be saying to the Medicaid offices to obtain prior authorization for Vyvanse. Mr. Painter responded that he would deal with that later and turned the discussion to other topics.

111. Accordingly, Mr. Painter and Shire were well aware that prior authorizations were being done by their sales staff, but did nothing to stop it. Shire knew that Vyvanse prescriptions in states where Vyvanse was not on the formulary list would be anemic without sales representative involvement in prior authorizations. Notably, when directly asked about prior authorizations, Mr. Painter did not say that it was against company policy to do prior authorizations. Nor did he say that Ms. Goldstein and other sales representatives should cease doing prior authorizations. Rather, Mr. Painter allowed Shire to reap the benefits of its sales representatives' misconduct, misconduct that Shire had itself directed.

L. Shire Made The Relators and Their Supervisor, Jeff Jackson, The Scapegoat When the Illinois Medicaid Agency Began To Suspect That Shire Sales Representatives Were Obtaining Prior Authorization For Their Doctors For Vyvanse Prescriptions.

112. Beginning in March of 2008, Mr. Jackson told the Relators that the Illinois Medicaid Agency began to suspect that it was Shire sales representatives who were calling to obtain prior authorization for Vyvanse prescriptions. At this same time, Mr. Jackson told the Relators and his other sales representatives that they should change their routine by, for example, calling the Illinois Medicaid agency on different days, at different times, and by using different names.

113. When asked by the Relators whether what they were doing was illegal, Mr. Jackson reassured the sales representatives that Shire was well aware of what they were doing, and it was perfectly legal. Beginning in the Spring of 2008, however, prior authorizations became more difficult to obtain.

114. In April 2008, Mr. Jackson again told the Relators and his other sales representatives that the State of Illinois was becoming suspicious. Mr. Jackson explained that a Shire employee in the government affairs department had received a complaint from the State of Illinois that they were suspicious that Shire sales representatives were the ones doing prior authorizations. As a consequence, he instructed Ms. Harris to make fewer prior authorization requests, although he told Ms. Hsieh to continue in the same manner.

115. It was important for Mr. Jackson to maintain some Vyvanse sales in his territory, which explains why he encouraged Ms. Hsieh to continue doing prior authorizations. Although the Relators had become nervous about what they were doing at this time, they were instructed by Mr. Jackson to follow the company's directives and were frequently reassured by

Mr. Jackson that their conduct was permissible and critical to keeping their jobs and for Shire's future.

116. In June 2008, however, Mr. Jackson told all of his Illinois sales representatives, including the Relators, to stop obtaining prior authorizations because doing so would help get Vyvanse on the Illinois formulary list for the following year. Shortly thereafter, however, he told Ms. Hsieh to continue trying to obtain prior authorizations with her top Vyvanse prescribing doctor, Dr. Yanamadala. Ultimately, though, Mr. Jackson told Ms. Hsieh that she, too, should stop trying to obtain prior authorizations.

117. In July 2008, Shire employees Tom Glavine and Jason Beranski interviewed Mr. Jackson and Ms. Hsieh about prior authorizations. Shortly thereafter, Shire put both employees on leave. In early July 2008, after Mr. Jackson and Ms. Hsieh were put on leave, Mr. O'Keefe and Mr. Painter held a conference call with the St. Louis North region. In that conference call, Mr. O'Keefe stated that it was not improper for sales representatives to access patient files.

118. Days later, Mr. Casto and Mr. Painter conducted a national telephone conference with all of its sales representatives purportedly to ensure that no sales representative was engaged in obtaining prior authorizations for his/her doctors or, in contrast to the previous conference call, accessing patient information. On this call, the sales representatives were instructed that it was impermissible to help the doctors obtain prior authorizations and demanded that all sales representatives sign an agreement that they were aware of the law and would act in conformity with it.

119. Shortly thereafter, Shire terminated the Relators because of the prior authorization work that they had been doing, despite the fact that Shire had instructed them to do so.

COUNT I
(Federal False Claims Act -- Making of False Claims and False Records)

120. Relators repeat paragraphs 1-119 above, as paragraph 120.

121. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

122. Prior to May 20, 2009, 31 U.S.C. § 3729(a) provided, in relevant part, liability for any person who –

- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

Section 3 further provides that in the event of a violation, such a person is “liable to the State for a civil penalty of not less than \$5,500 and not more than \$11,000, plus 3 times the amount of damages which the State sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.”

123. On May 20, 2009, 31 U.S.C. § 3729(a) was amended to provide, in relevant part, liability for:

- (1) any person who –

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

124. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

125. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

126. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

127. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

128. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

129. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians across the United States provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

130. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

131. As a result, Shire violated Sections 3729(a)(1) and (2); and Sections 3729(a)(1)(A) and (B) as amended, of the federal False Claims Act and caused the federal government to suffer millions of dollars of actual damages.

132. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

133. The United States Government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

134. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT II

(Federal False Claims Act -- Shire's False Statements)

135. Relators repeat paragraphs 1-119 above, as paragraph 135.

136. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

137. Prior to May 20, 2009, 31 U.S.C. § 3729(a) provided, in relevant part, liability for any person who –

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

Section 3 further provides that in the event of a violation, such a person is “liable to the State for a civil penalty of not less than \$5,500 and not more than \$11,000, plus 3 times the amount of damages which the State sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.”

138. On May 20, 2009, 31 U.S.C. § 3729(a) was amended to provide, in relevant part, liability for:

- (1) any person who –

- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

139. Pursuant to Shire's prior authorization scheme, Shire sales representatives called state Medicaid agencies to obtain prior approval for Vyvanse prescriptions.

140. Shire sales representatives were directed to conduct such prior authorizations by their Shire supervisors.

141. During those calls, Shire sales representatives represented that the physician on whose behalf they were attempting to obtain prior authorization for a Vyvanse prescription had determined that the prescription met pre-approval criteria for Medicaid reimbursement set forth in that state. That representation was false.

142. Moreover, the Shire sales representatives who called Medicaid to obtain prior approval did not disclose that he/she was a Shire sales representative, and that he/she therefore had a direct financial interest in the resulting Vyvanse prescription.

143. Shire made the misrepresentation and failed to disclose its involvement to Medicaid for the purpose of getting a false and fraudulent Vyvanse prescription paid for by Medicaid.

144. Accordingly, Shire made false statements to get a false claim paid, which violates 31 U.S.C. § 3729(a)(2), or 31 U.S.C. § 3729(a)(1)(B), as amended.

145. By reason of Shires' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT III

(Illinois Whistleblower Reward and Protection Act -- Making of False Claims and False Records)

146. Relators repeat paragraphs 1–119 above, as paragraph 147.

147. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1, *et seq.*

148. Section 3 of the Illinois Whistleblower Reward and Protection Act provides liability for any person who –

- (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State.

149. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

150. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

151. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

152. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

153. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

154. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Illinois provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

155. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

156. As a result, Shire violated 740 ILCS 175/3(a)(1) and (2) of the Illinois Whistleblower Reward and Protection Act and caused the State of Illinois to suffer millions of dollars of actual damages.

157. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

158. The Illinois government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

159. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT IV

(Illinois Whistleblower Reward and Protection Act -- Shire's False Statements)

160. Relators repeat paragraphs 1-119 above, as paragraph 161.

161. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1, *et seq.*

162. Section 3 of the Illinois Whistleblower Reward and Protection Act provides liability for any person who –

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State.

163. Pursuant to Shire's prior authorization scheme, Shire sales representatives called Illinois Medicaid agencies to obtain prior approval for Vyvanse prescriptions.

164. Shire sales representatives were directed to conduct such prior authorizations by their Shire supervisors.

165. During those calls, Shire sales representatives represented that the physician on whose behalf they were attempting to obtain prior authorization for a Vyvanse prescription had determined that the prescription met pre-approval criteria for Medicaid reimbursement set forth in that Illinois. That representation was false.

166. Moreover, the Shire sales representatives who called Medicaid to obtain prior approval did not disclose that he/she was a Shire sales representative, and that he/she therefore had a direct financial interest in the resulting Vyvanse prescription.

167. Shire made the misrepresentation and failed to disclose its involvement to Medicaid for the purpose of getting a false and fraudulent Vyvanse prescription paid for by Medicaid.

168. Accordingly, Shire made false statements to get a false claim paid, which violates 740 ILCS 175/3(a)(2) of the Illinois Whistleblower Reward and Protection Act.

169. By reason of Shires' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT V
(California False Claims Act)

170. Relators repeat paragraphs 1-119 above, as paragraph 172.

171. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code §§ 12650, *et seq.*

172. Cal. Gov't Code § 12651(a) provides liability for any person who –

- (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.
- (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision.

173. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

174. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

175. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

176. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

177. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

178. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in California provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

179. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

180. As a result, Shire violated Cal. Gov't Code § 12651(a)(1) and (2) of the California False Claims Act and caused the State of California to suffer millions of dollars of actual damages.

181. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

182. The California government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

183. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT VI
(Delaware False Claims and Reporting Act)

184. Relators repeat paragraphs 1-119 above, as paragraph 184.

185. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201, *et seq.*

186. Del. Code Ann. tit. 6, § 1201(a) provides liability for any person who –

- (1) Knowingly presents, or causes to be presented to an officer or employee of the Government a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government;....

187. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

- (1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration

(including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

188. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

189. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

190. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

191. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

192. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Delaware provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

193. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

194. As a result, Shire violated Del. Code Ann. tit. 6, § 1201(a)(1) and (2) of the Delaware False Claims and Reporting Act and caused the State of Delaware to suffer millions of dollars of actual damages.

195. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

196. The Delaware government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

197. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT VII
(Florida False Claims Act)

198. Relators repeat paragraphs 1-119 above, as paragraph 198.

199. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. §§ 68.081, *et seq.*

200. Fla. Stat. § 68.082(2) provides liability for any person who –

- (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;....

201. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

202. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

203. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

204. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

205. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

206. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Florida provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

207. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

208. As a result, Shire violated Fla. Stat. § 68.082(2)(a) and (b) of the Florida False Claims Act and caused the State of Florida to suffer millions of dollars of actual damages.

209. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

210. The Florida government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

211. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT VIII
(Georgia False Medicaid Claims Act)

212. Relators repeat paragraphs 1-119 above, as paragraph 212.

213. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168, *et seq.*

214. Ga. Code Ann. § 49-4-168.1 provides liability for any person who –

- (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;....

215. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be

made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

216. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

217. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

218. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

219. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

220. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Georgia provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

221. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing

the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

222. As a result, Shire violated Ga. Code Ann. § 49-4-168.1(1) and (2) of the Georgia False Medicaid Claims Act and caused the State of Georgia to suffer millions of dollars of actual damages.

223. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

224. The Georgia government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

225. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT IX
(Massachusetts False Claims Act)

226. Relators repeat paragraphs 1–119 above, as paragraph 226.

227. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5, *et seq.*

228. Mass. Gen. Laws ch. 12, § 5B provides liability to any person who –

- (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;....

229. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

230. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

231. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

232. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

233. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

234. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Massachusetts provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

235. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

236. As a result, Shire violated Mass. Gen. Laws ch. 12, § 5B(1) and (2) of the Massachusetts False Claims Act and caused the State of Massachusetts to suffer millions of dollars of actual damages.

237. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

238. The Massachusetts government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

239. By reason of Defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT X
(Michigan Medicaid False Claims Act)

240. Relators repeat paragraphs 1–119 above, as paragraph 240.

241. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601, *et seq.*

242. Mich. Comp. Laws § 400.607 provides, in part, that:

- (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.

243. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

- (1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

244. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

245. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

246. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

247. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

248. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Michigan provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

249. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

250. As a result, Shire violated Mich. Comp. Laws § 400.607 of the Michigan Medicaid False Claims Act and caused the State of Michigan to suffer millions of dollars of actual damages.

251. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

252. The Michigan government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

253. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XI

(Nevada Submission of False Claims to State or Local Government Act)

254. Relators repeat paragraphs 1-119 above, as paragraph 254.

255. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. §§ 357.010, *et seq.*

256. Nev. Rev. Stat. § 357.040(1) provides liability to any person who –

- (a) Knowingly presents or causes to be presented a false claim for payment or approval.
- (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim....

257. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

258. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

259. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

260. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

261. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

262. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Nevada provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

263. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

264. As a result, Shire violated Nev. Rev. Stat. § 357.040(1)(a) and (b) of the Nevada Submission of False Claims to State or Local Government Act and caused the State of Nevada to suffer millions of dollars of actual damages.

265. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

266. The Nevada government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

267. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XII
(New Hampshire False Claims Act)

268. Relators repeat paragraphs 1-119 above, as paragraph 268.

269. This is a claim for treble damages and civil penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61, *et seq.*

270. N.H. Rev. Stat. Ann. § 167:61-b(1) provides liability to any person who –

- (a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
- (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.....

271. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

272. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

273. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

274. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

275. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

276. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in New Hampshire provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

277. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

278. As a result, Shire violated N.H. Rev. Stat. Ann. § 167:61-b(I)(a) and (b) of the New Hampshire False Claims Act and caused the State of New Hampshire to suffer millions of dollars of actual damages.

279. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

280. The New Hampshire government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

281. By reason of Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XIII
(New Jersey False Claims Act)

282. Relators repeat paragraphs 1-119 above, as paragraph 282.

283. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*

284. N.J. Stat. Ann. § 2A:32C-3 provides liability to any person who –

- a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
- b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;....

285. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

286. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

287. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

288. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

289. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

290. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in New Jersey provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

291. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

292. As a result, Shire violated N.J. Stat. Ann. § 2A:32C-3(a) and (b) of the New Jersey False Claims Act and caused the State of New Jersey to suffer millions of dollars of actual damages.

293. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

294. The New Jersey government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

295. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XIV

(Oklahoma Medicaid False Claims Act)

296. Relators repeat paragraphs 1–119 above, as paragraph 296.

297. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §§ 5053, *et seq.*

298. Okla. Stat. tit. 63 § 5053.1(B) provides liability to any person who –

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;....

299. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

300. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

301. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

302. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

303. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

304. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Oklahoma provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

305. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

306. As a result, Shire violated Okla. Stat. tit. 63 § 5053.1(B)(1) and (2) of the Oklahoma Medicaid False Claims Act and caused the State of Oklahoma to suffer millions of dollars of actual damages.

307. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

308. The Oklahoma government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

309. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XV
(Tennessee Medicaid False Claims Act)

310. Relators repeat paragraphs 1–119 above, as paragraph 310.

311. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.*

312. Tenn. Code Ann. § 71-5-182(a)(1) provides liability to any person who –

- (A) Presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing such claim is false or fraudulent;
- (B) Makes, uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;....

313. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

- (1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration

(including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

314. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

315. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

316. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

317. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

318. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Tennessee provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

319. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

320. As a result, Shire violated Tenn. Code Ann. § 71-5-182(a)(1)(A) and (B) of the Tennessee Medicaid False Claims Act and caused the State of Tennessee to suffer millions of dollars of actual damages.

321. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

322. The Tennessee government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

323. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XVI
(Texas Medicaid Fraud Protection Act)

324. Relators repeat paragraphs 1–119 above, as paragraph 324.

325. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Protection Act, Tex. Hum. Res. Code Ann. §§ 36.001, *et seq.*

326. Tex. Hum. Res. Code Ann. § 36.002 provides liability to any person who –

- (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
- (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
- ...
- (4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
 - ...
 - (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;....

327. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing,

or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

328. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

329. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

330. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

331. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

332. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Texas provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

333. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

334. As a result, Shire violated Tex. Hum. Res. Code Ann. § 36.002(1), (2) and (4)(B) of the Texas Medicaid Fraud Protection Act and caused the State of Texas to suffer millions of dollars of actual damages.

335. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

336. The Texas government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

337. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XVII
(District of Columbia False Claims Act)

338. Relators repeat paragraphs 1–119 above, as paragraph 338.

339. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §§ 2-308.03, *et seq.*

340. D.C. Stat. Ann. § 2-308.14(a) provides liability to any person who –

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;....

341. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

342. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

343. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

344. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

345. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

346. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in District of Columbia provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

347. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

348. As a result, Shire violated D.C. Stat. Ann. § 2-308.14(a)(1) and (2) of the District of Columbia False Claims Act and caused the District of Columbia to suffer millions of dollars of actual damages.

349. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

350. The government of the District of Columbia, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

351. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

Count XVIII
(Hawaii False Claims Act)

352. Relators repeat paragraphs 1-119 above, as paragraph 352.

353. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Hawaii Rev. Stat. §§ 661-21, et seq.

354. Haw. Rev. Stat. § 661-21(a) provides liability to any person who –

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;....

355. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

356. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

357. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

358. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

359. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

360. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Hawaii provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

361. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

362. As a result, Shire violated Haw. Rev. Stat. § 661-21(a)(1) and (2) of the Hawaii False Claims Act and caused the State of Hawaii to suffer millions of dollars of actual damages.

363. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

364. The Hawaii government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

365. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

Count XIX
(Indiana False Claims and Whistleblower Protection Act)

366. Relators repeat paragraphs 1-119 above, as paragraph 366.

367. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1, *et seq.*

368. Ind. Code § 5-11-5.5-2(b) provides liability to any person who knowingly or intentionally –

- (1) presents a false claim to the state for payment or approval;

- (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;....

369. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

370. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

371. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

372. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

373. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

374. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Indiana provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

375. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

376. As a result, Shire violated Ind. Code § 5-11-5.5-2(b)(1) and (2) of the Indiana False Claims and Whistleblower Protection Act and caused the State of Indiana to suffer millions of dollars of actual damages.

377. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

378. The Indiana government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

379. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XX
(Louisiana False Claims Act)

380. Relators repeat paragraphs 1–119 above, as paragraph 380.

381. This is a claim for treble damages and civil penalties under the Louisiana False Claims Act, La. Rev. Stat. 46: §§ 437.1, *et seq.*

382. La. Rev. Stat. 46: § 438.2.A. provides that “[n]o person shall solicit, receive, offer, or pay any remuneration ...”:

(2) In return for purchasing ... any good ... for which payment may be made, in whole or in part, under the medical assistance programs.

383. La. Rev. Stat. 46: § 438.3.A. provides that “[n]o person shall knowingly present or cause to be presented a false or fraudulent claim.”

384. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

385. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

386. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

387. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

388. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

389. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Louisiana provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

390. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

391. As a result, Shire violated La. Rev. Stat. 46: §§ 438.2.A(2) and 438.3.A. of the Louisiana False Claims Act and caused the State of Louisiana to suffer millions of dollars of actual damages.

392. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

393. The Louisiana government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

394. By reason of Defendants' acts, the State of Louisiana and has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXI
(Montana False Claims Act)

395. Relators repeat paragraphs 1-119 above, as paragraph 395.

396. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code §§ 17-8-401, *et seq.*

397. Mont. Code § 17-8-403(1) provides liability to any person causing in excess of \$500 of damage to the government who –

- (a) knowingly present[s] or caus[es] to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

- (b) knowingly mak[es], us[es], or caus[es] to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;....

398. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

399. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

400. Shire’s “ride along” and “speaker” programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

401. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

402. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

403. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Montana provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

404. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

405. As a result, Shire violated Mont. Code § 17-8-403(1)(a) and (b) of the Montana False Claims Act and caused the State of Montana to suffer millions of dollars of actual damages.

406. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

407. The Montana government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

408. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXII
(New Mexico Medicaid False Claims Act)

409. Relators repeat paragraphs 1–119 above, as paragraph 409.

410. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. §§ 27-14-1, *et seq.*

411. N.M. Stat. § 27-14-4 provides liability to any person who –

- A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent; ...
- C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;....

412. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

413. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

414. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

415. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

416. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

417. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in New Mexico provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

418. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

419. As a result, Shire violated N.M. Stat. § 27-14-4A. and C. of the New Mexico Medicaid False Claims Act and caused the State of New Mexico to suffer millions of dollars of actual damages.

420. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

421. The New Mexico government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

422. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXIII
(New York False Claims Act)

423. Relators repeat paragraphs 1-119 above, as paragraph 423.

424. This is a claim for treble damages and civil penalties under the New York False Claims Act, State Fin. Law §§ 187, *et seq.*

425. State Fin. Law § 189.1 provides liability to any person who –

- (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

- (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;....

426. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

427. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

428. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

429. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

430. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

431. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in New York provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

432. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

433. As a result, Shire violated State Fin. Law § 189.1(a) and (b) of the New York False Claims Act and caused the State of New York to suffer millions of dollars of actual damages.

434. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

435. The New York government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

436. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXIV
(Rhode Island False Claims Act)

437. Relators repeat paragraphs 1-119 above, as paragraph 437.

438. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1, *et seq.*

439. R.I. Gen. Laws § 9-1.1-3(a) provides liability to any person who —

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;....

440. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing,

or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

441. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

442. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

443. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

444. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

445. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Rhode Island provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

446. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

447. As a result, Shire violated R.I. Gen. Laws § 9-1.1-3(a)(1) and (2) of the Rhode Island False Claims Act and caused the State of Rhode Island to suffer millions of dollars of actual damages.

448. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

449. The Rhode Island government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

450. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXV
(Virginia Fraud Against Taxpayers Act)

451. Relators repeat paragraphs 1-119 above, as paragraph 451.

452. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1, *et seq.*

453. Va. Code § 8.01-216.3(A) provides liability to any person who –

- (1) Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or

fraudulent claim paid or approved by the Commonwealth;....

454. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C.

§ 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute ("AKS"), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

455. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

456. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

457. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

458. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

459. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Virginia provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

460. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

461. As a result, Shire violated Va. Code § 8.01-216.3(A)(1) and (2) of the Virginia Fraud Against Taxpayers Act and caused the State of Virginia to suffer millions of dollars of actual damages.

462. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

463. The Virginia government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

464. By reason of Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual

damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

COUNT XXVI
(Wisconsin False Claims Act)

465. Relators repeat paragraphs 1–119 above, as paragraph 465.

466. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. § 20.931.

467. Wis. Stat. § 20.931(2) provides liability to any person who –

- (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance;
- (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance;....

468. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b)(1)(A), also known as the Anti-Kickback Statute (“AKS”), states that:

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives [or, in subsection (2), offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b.

469. Any claim to a state Medicaid agency for payment of a prescription contains an implied certification that the claim was not the result of an illegal remuneration of the type described in 42 U.S.C. § 1320a-7b(b)(1)(A).

470. Shire's "ride along" and "speaker" programs provided remuneration to physicians in exchange for the writing of prescriptions for Vyvanse.

471. Similarly, Shire's prior authorization scheme provided an "in kind" benefit to physicians -- in the form of administrative services -- to induce and encourage those physicians to write Vyvanse prescriptions.

472. The above described remuneration are the type of illegal remunerations described in 42 U.S.C. § 1320a-7b(b)(1)(A).

473. Induced by Shire's illegal remunerations to prescribe Vyvanse, physicians in Wisconsin provided prescriptions to their ADHD patients. In turn, those patients supplied the prescriptions to pharmacies, which submitted the prescriptions to Medicaid for payment.

474. The implied certification of compliance with the AKS supplied by pharmacies submitting claims for Vyvanse prescriptions was false. Accordingly, by providing the illegal remuneration detailed above, Shire caused to be presented to Medicaid a false and fraudulent claim for payment.

475. As a result, Shire violated Wis. Stat. § 20.931(2)(a) and (b) of the Wisconsin False Claims Act and caused the State of Wisconsin to suffer millions of dollars of actual damages.

476. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false.

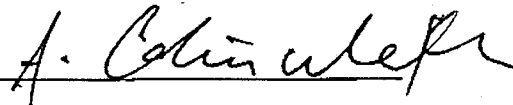
477. The Wisconsin government, unaware of the falsity of the records and claims caused to be made by Defendants, paid and continues to pay claims that would not have been paid but for the acts and/or conduct of Defendants as alleged herein.

478. By reason of Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff-Relators Anita Hsieh, Kara Harris, and Ian Clark request that judgment be entered in their favor and against Shire PLC and Shire US Inc. for actual damages, treble damages and penalties, and attorneys' fees and costs, and that the Court award any additional relief it deems appropriate.

Dated: November 6, 2009

ANITA HSIEH, KARA HARRIS, and IAN CLARK

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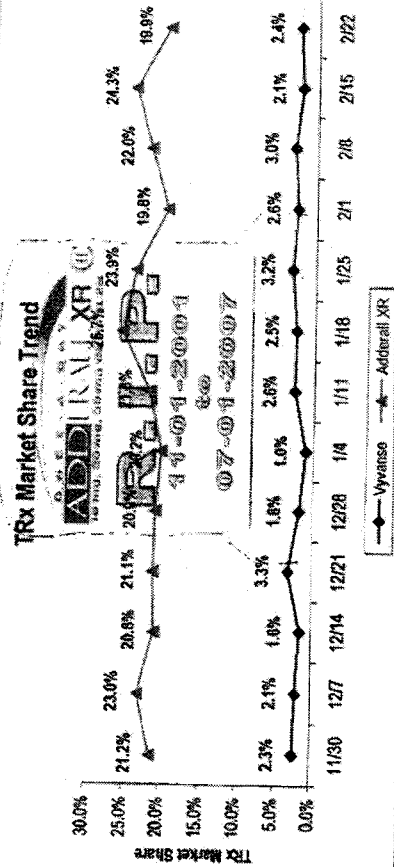
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EXHIBIT A

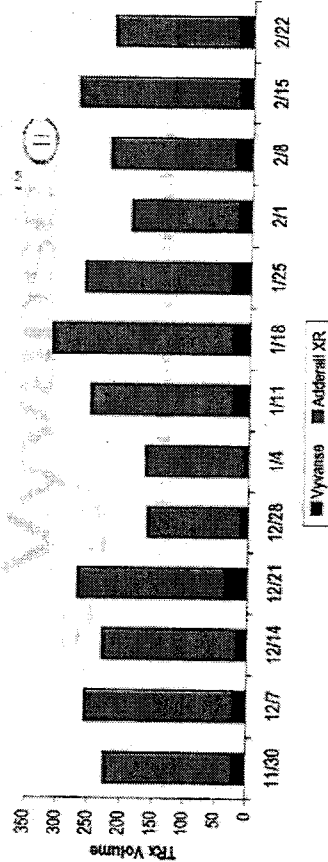
ADHD Weekly Report - 02/22/2008

BUST THE BLOCKBUSTER

Territory F0409



TRx Volume Trend



DAYTRANA POINTS

Q4 Daytrana Rx's*

100

QTD Daytrana Rx's

78

Q1 Daytrana Pace

127

Q1 Daytrana Points

270

Projected Q1 Rank

2

Daytrana 10 mg
 15 mg
 20 mg
 30 mg

methamphetamine hydrochloride (extended release)

TARGETS WHO HAVE TRIED VYVANSE

F0409 - Champaign West, IL - Territory Totals

# of Targets That Have Tried Vyvanse Since Launch	% of Total Targets	# of Targets That Have Tried Vyvanse Within Last 4 Weeks	% of Total Targets
39	52%	28	37%

North Central Zone Averages

Avg. # of Targets That Have Tried Vyvanse Since Launch	% of Total Targets	Avg. # of Targets That Have Tried Vyvanse Within Last 4 Weeks	% of Total Targets
41	55%	31	42%

* Q4 Baseline is based on weekly Daytrana Rx's for 9/29-12/28 for reporting purposes only

* This report should be used for directional purposes only

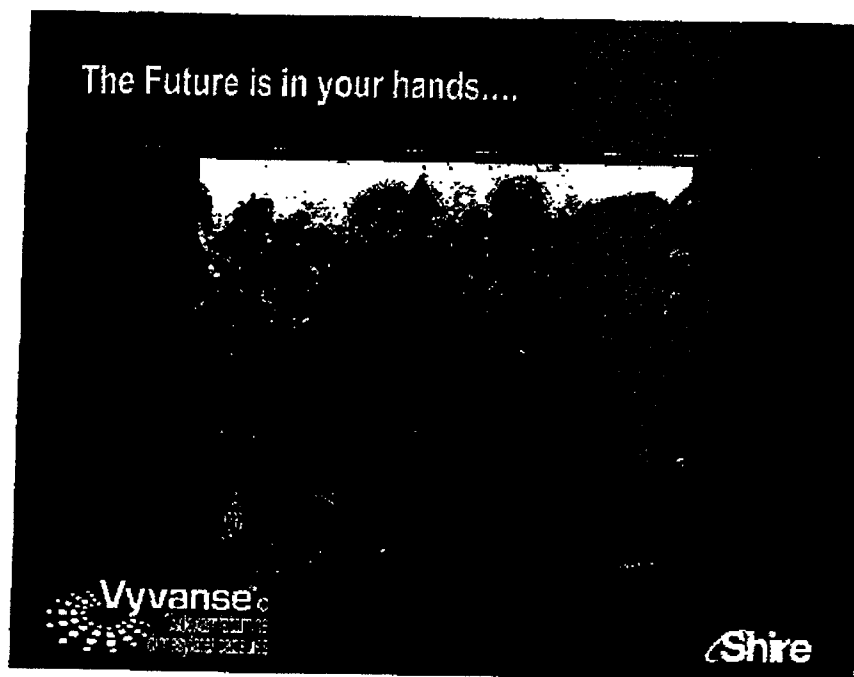
EXHIBIT B

Launch Objectives

**Rapidly replace Adderall XR®
prescriptions with VYVANSE™**



EXHIBIT C

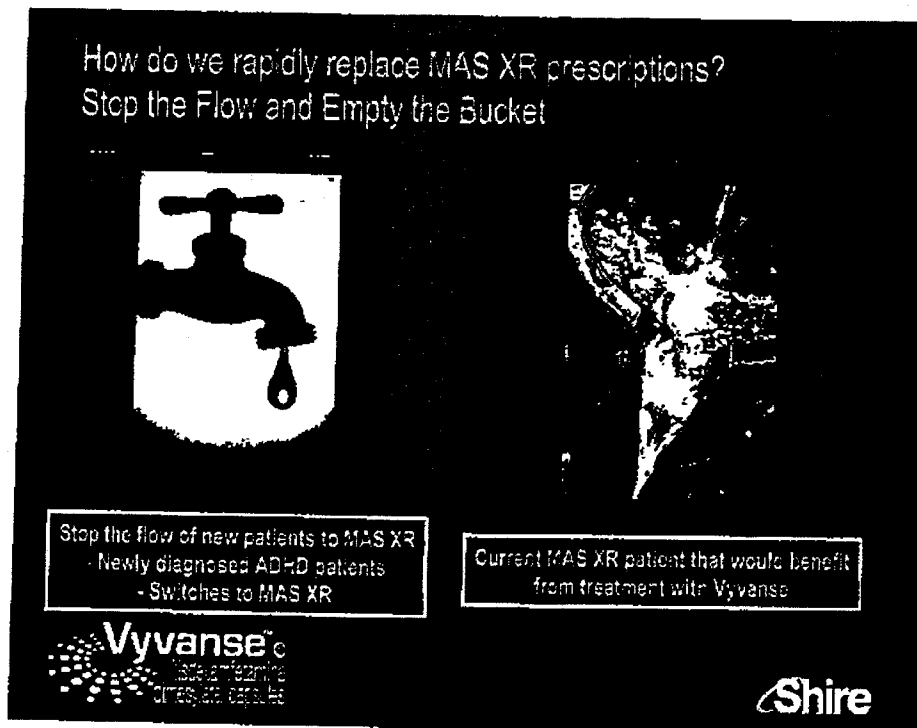


The future is in your hands!

Over the next 3 months, we must establish **VYVANSE** as physicians first choice when prescribing ADHD medications.

INTERNAL USE ONLY

EXHIBIT D



How do we rapidly replace MAS XR prescriptions?

First, we must stop the flow of current MAS XR patients. How do we do this? We do this by convincing physicians to prescribe VYVANSE in newly diagnosed patients. We convince physicians to prescribe VYVANSE in those patients that physicians would typically convert to MAS XR from other products.

Secondly, we must empty the bucket of current MAS XR patients. These are the patients that would Benefit from treatment with Vyvanse.

It all boils down to replace MAS XR in physicians minds with **VYVANSE**. If we are successful, we will eventually rapidly replace MAS XR prescriptions with Vyvanse.

EXHIBIT E

Why would I convert a patient that is doing well on Adderall XR?

Excellent question Doctor. The efficacy and safety of Vyvanse and Adderall XR compared with placebo in children ages 6-12 with ADHD was assessed in a controlled classroom environment. A 3-week dose-titration period was used to determine the optimal dose of Adderall XR (10 mg, 20 mg, or 30 mg) for each subject. Patients were then randomized into one of three groups; Vyvanse, Adderall XR or placebo. As a reminder, the purpose of this study was to evaluate the efficacy of Vyvanse, vs placebo, following optimization with Adderall XR.

- ✓ Robust effect at the first time point tested that was maintained through 12 hours

p.9: PERMP Math - Attempted Score from the first time point measured

p.10: Clinicians rated 32% of patients taking Vyvanse as "very much improved"

- ✓ Vyvanse provided consistent time to maximum concentration from patient to patient

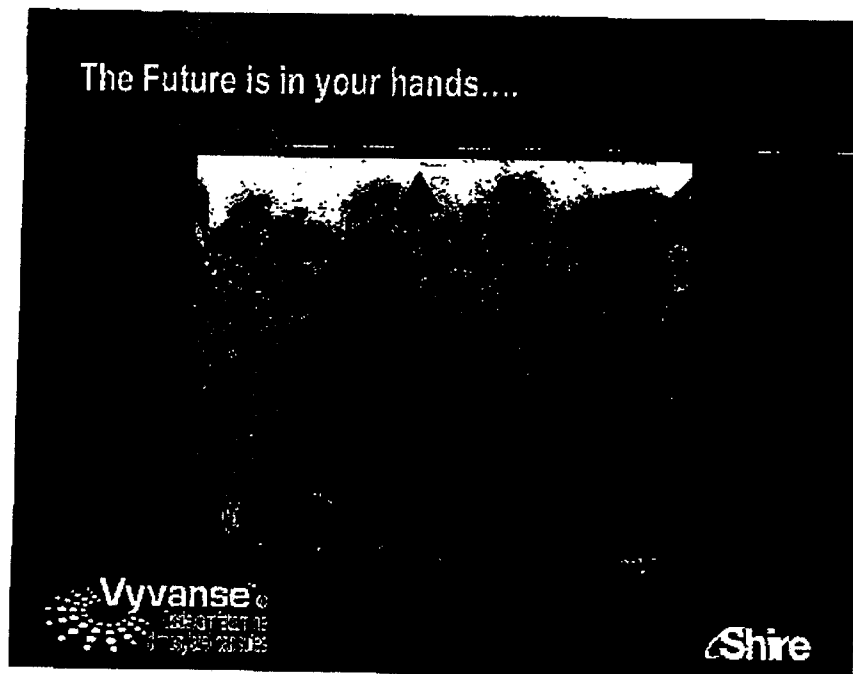
p.5: Release of the active ingredient in Vyvanse does not rely on gastrointestinal factors such as GI transit time and gastric pH

In a naturalistic study...

- ✓ Parents reported significant efficacy throughout the day, even at 6 PM

p.7: Vyvanse provided significant efficacy throughout the day, even at 6 PM

EXHIBIT F



Just like the Allied forces on D-Day, we have secured the beachhead. The war does not end here. Once a solid beachhead was established, the allied troops knew they had a chance at success. They also understood that a lot of hard work remained if they were going to win the war.

We already secured our beachhead...the early prescribers! We will leverage these early prescribers to share their clinical experience with other physicians. Success stories must travel through you and through our marketing programs, to allow us to gain entry as a mainstream ADHD product.

The future is in your hands! You will determine if VYVANSE crosses the chasm and into the mainstream in your territory.

INTERNAL USE ONLY

EXHIBIT G

REDACTED

EXHIBIT H

REDACTED

EXHIBIT I



Field Coaching Report

Representative: Anita Hsieh Territory #: F0407
 Rep Level: 1 - Professional Sales Representative
 Area Worked: Granite City / Alton Date Worked: December 3 - 5, 2007
 Regional Director: Jeff Jackson Date Last Field Contact: October 31 & November 1, 2007
 Sales Through: Sep-07 Call Activity Month: October 2007

VYVANSE - Sales Performance												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Market Share							0.44	1.84	2.87			
National Ranking							466	427	419			
Market Share Growth								1.84	2.87			
Market Share Growth National Rank								427	410			

DAYTRANA - Sales Performance												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Market Share				1.22	1.8	1.99	1.51	1.19	1.57			
National Ranking								532				
Market Share Growth				0.29	0.87	1.06	0.56	0.24	0.63			
Market Share Growth National Rank				299	96	60	114	254	140			

Call Activity												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
1-5	Reach								37	35		
	Frequency								29	26		
	Super Frequency								18	17		
	Daily Call Average								5.11	2.25		
51-75	Reach								13	7		
	Frequency								6	5		
	Daily Call Average								1.21	0.67		
Total Daily Call Average									6.37	5.33		

Follow-up from Previous Field Coaching Reports (Rep Provided)

Targeting - Territory Management - Administrative												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Reach												D2
Frequency												D2
Frequency												D3
Process Strategy												
Use of Sales Reports												D2
Use of Company Funds												D3
Current Maintenance of Territory Records / Administrative												D4
Comments: Rep Competencies/Observations												
<p>Use of Sales Reports (this includes all reports received from the corporate office)</p> <p>Understanding sales reports so that they are analyzed for market trends, reach/frequency impact and even return on investment with regards to spending. Excellence is the ability to compare numbers/data against the region, zone, nation with ms and ms growth. They should also be able to calculate their bonus. They should have an in depth understanding of the trend reports and what they mean and the exponent etc.</p> <p>As we discussed, listed are the reports that you should always have available: Xponent (ACE), Sales Reports (all products), Bonus Report, Call Activity Summary (full year), Call Activity Trend, Targeting Sheet (full year). The more we understand our business, the better we can manage it. That's why having these reports available and being able to use them to help analyze & manage your business is so important.</p> <p>Itinerary</p> <p>An excellent itinerary is one that shows not only best days, but more importantly specific times of the day in which the most time can be spent with the physician. An itinerary should be continually updated with days, times, addresses, as well as days and times at alternate locations. Itineraries should be designed in a geographic nature that allows for the least amount of travel time throughout the day and every day should be filled with an adequate number of physicians to surpass daily call objectives. A master itinerary as well as a daily itinerary should be maintained.</p>												

Knowledge and Application												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Product and Competitive Knowledge												D3
Knowledge of Prescribing Information												D2
Knowledge of Non-Prescribing Information												D3
Comments: Rep Competencies/Observations												
<p>Product and Competitive Knowledge</p> <p>Competent reps are continually enhancing their knowledge: disorder, product, competition, industry, Managed Care. Excellence is taking the initiative to read the studies over and over, each time looking for other ways to use the information in a selling situation. Excellence in this area is knowing your competitors better than they know themselves through company created training as well as information found in the offices, or doing research on the products.</p>												

Selling Skills												
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Pre-Call Plan/Setting Objectives (Qualifying and Identifying patients)												D2
Listening Skills												D3
Probing to Create Dialogue												D2
Listening Skills												D3
Delivery of a Complete Selling Message												D3
Transitioning to Second Selling Message												D2
Use of Visual Aid / Reprints												D4
Ability to Handle Objections - 5 C's												D2
Closing Skills: Gaining Commitment/ Utilization of Promotional/Support Items												D2
Selling to Entire Office/ Rapport with Office												D3
Post-Call Analysis: Call Notes/ Setting Next Call Objectives												D2
Comments: Rep Competencies/Observations												
<p>5. Delivery of Complete Selling Message</p> <p>Delivering a complete selling message is more than just going cover to cover through the visual aid. Competency in this area consists of memorizing and understanding the suggested presentation as a guide to then use the background knowledge on the physician to tailor a specific message based upon the targeted patient profile. A complete message is using all of the necessary information throughout the visual aid to discuss the features and benefits of our products. Delivering a complete message is the ability to SELL the product throughout the presentation and most importantly asking for the business.</p> <p>I think we hit on something during this field contact, with the way you role-played. It worked out great when you did practiced it straight through multiple times in a row. I strongly recommend you continue to do this with frequency throughout the day. You were rocking and rolling by the third time. By doing it straight through it helps to not over think it. By doing it three times in a row, it helps to reduce the "fluff" and you automatically add more impact statements. Also, your confidence shot up from the first time, you explained it more clearly, and you told the doctor how this information should be interpreted. NICE!!! We also worked on the call continuum and building off of the last message you had with that physician.</p>												
<p>11. Selling to Entire Office/Rapport with Office</p> <p>This encompasses more than just knowing the staff's name; this is knowing the office inside and out, as if you were the office manager. Knowing the staff by name, as well as likes & dislikes and understanding the role of each person within the office. Excellence comes in using these relationships to gain access and more importantly commitments.</p> <p>You have developed great relationships with many of your offices, especially with your top rank physicians. Those relationships have definitely been beneficial. Example - offices calling you when problems occur, assisting them with doing PAs, etc. In addition to having strong relationships where they want to help "you", continue to sell each staff so they become STRONG advocates for your products. An army of staff who believe in your products and believe in you will sell for you when you aren't present to sell. It can have SIGNIFICANT benefit to your business AND to the patients.</p>												

2007 Annual Objectives	
Objective & Description	Action Steps

PLAN OF ACTION	
S.M.A.R.T. Objectives (Specific, Motivating, Attainable, Relevant, Trackable):	
SELLING SKILLS	
Delivery of a Complete Selling Message <input type="button" value="v"/> Call Continuum - Taking advantage of any areas of opportunity where you can increase the doctor's buy in to upgrade AXR patients to VVV. (Strengthening their believes and the action they take.) To Identify Areas: What aspects of our key selling points are they not fully understanding? (Clear up any confusion) What has been the outcome of the call and the action that they've taken? (Have they giving the same response multiple calls?) What do I want that action or outcome to look like? Then SPECIFICALLY, what will you on the next call to take advantage of that opportunity? OBJECTIVE: During your post call (when planning for your next call objective), 1 very specific way you'll build off of that call. (No more than 3)	
LING SKILLS	
Delivery of a Complete Selling Message <input type="button" value="v"/> GLOBAL - Evaluate Sales Message: Ways to state your sales point more clearly. Specific ways to sell the "So what this means to your patients." OBJECTIVE: After post call session, 1 SPECIFIC way you can take your message to the next level. What would that look like? Practice w/out getting bogged down.	
GENERAL COMMENTS	
General Comments <input type="button" value="v"/> Let's find a way to let "Anita Unleashed" out consistently every day, on every call. The roll play, WITHOUT STOPPING, multiple times in a roll, is a great step in order to do that. Recap of what we worked on - Role play message straight through, back to back minimum 3 times in row. SELL IT!!! A Few Key Elements to Your Message: Clearly explain what your showing the doctor. They have to understand what they're looking at in order for you to be able to sell it. Then SELL IT!!! Let them know them know it's great results. Sell them on the importance to the patient. Tell them what this data should mean to them. Then check in to make sure they're on the same page. A Few Critical Impact Factors: 1. Confidence in what you are saying; 2. Impact adjectives & adverbs; 3. Your message, or any part of your message, cannot be a "TASK"; 4. Have purpose with every page, and a vision for the call (Remember - if you have a specific clear picture of where you are and where you want to get, then you can focus on steps to achieve that vision); 5. Watch your pace. Be purposeful in slowing yourself down at times throughout your sales message, especially when you are talking about the	

Representative Anita HsiehTerritory F0467and Director Jeff JacksonDate Last Field October 31 & November
Contact 1, 2007Date Worked December 3 - 5, 2007

Shire Leadership DNA
Accountability & Ownership "Understands work plan and carries out tasks against it to ensure that objectives are completed in a timely and effective manner. Tends to all of the necessary details in accomplishing work results; does not allow things to "slip through the cracks". When asked, follows through immediately on inquiries, requests, and/or complaints from patients, caretakers, physicians, etc."
Developing Organizational Capability "Demonstrates a willingness to draw upon the skills of stronger employees for development opportunities. Seeks out help and guidance from Regional Director and experienced Sales Representatives."
Judgment & Decision-Making "Focuses attention on targeted physicians and understands what steps need to be taken in order for sales goals to be met."
Embracing Change "Demonstrates willingness to change ideas or perceptions based on new information or contrary evidence."



Representative Signature: _____

Date: _____

Regional Director Signature: _____

Date: _____

FLEET VEHICLE CHECKLIST

What is the Current Mileage of the Vehicle?

 MILES

YES NO

Does the Vehicle Appear to Have Any Exterior Damage?

If Yes, Please Explain:

Does the Vehicle Appear to Have Any Interior Damage?

If Yes, Please Explain:

Does the Vehicle Show Evidence of Smoking or Smell Like Smoke?

Does the Vehicle Show Evidence of Having Been Used for Transporting Pets (Animals)?

Is the Driver's Manual Available for Use/Reference and kept in the Console or Glove Compartment of the Vehicle?

If No, Please Explain:

Is the Vehicle Registration kept in the Console or Glove Compartment of the Vehicle?

If No, Please Explain:

Is the Vehicle Insurance Card Current and kept in the Console or Glove Compartment of the Vehicle?

If No, Please Explain:

Is the Maintenance Coupon Book kept in the Console or Glove Compartment of the Vehicle?

If No, Please Explain:

Is a Copy of the Accident/Loss Report kept in the Console or Glove Compartment of the Vehicle?

If No, Please Explain:

Date:

December 3 - 5, 2007

Representative:

Anita Hsieh

Territory #: F0407

Regional Director:

Jeff Jackson

Location: Granite City / Alton